

***Preliminary Amendment***

Page 5

Applicants : Fayrer-Hosken, et al.

Serial No. 10/019,643

Filed: December 28, 2002

Attorney Docket No.: 235.0030 0101

Title: METHOD AND COMPOSITION FOR AFFECTING REPRODUCTIVE SYSTEMS

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**Remarks**

Claims 1-3, 10, 11, 24-26, and 30-40 having been cancelled, without prejudice, and claims 4, 6-9, 12-17, 21, 23, 27 and 28 having been amended. The claims presently pending in the above-identified patent application are claims 4-9, 12-23, and 27-29.

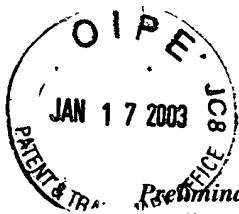
Recitation of "reproductive condition" in amended claims 4, 6, 7, 8 and 9 is supported by the specification at, for example, page 4, lines 17-20.

Recitation of "undesirable behavior as a result of reproductive activity or reproductive problems" as a reproductive disease, disorder or condition in amended claims 6, 7 and 9 is supported by the specification at, for example, page 18, lines 23-27.

Claims 12-17, 21, 23, 27 and 28 have been amended to correct dependencies in view of the cancellation of claims.

**Response to Restriction Requirement**

In response to the Restriction Requirement mailed December 24, 2002, Applicants elect, with traverse, Group III (claims 4-9, 12-23, and 27-29), drawn to a method for treating or preventing a reproductive disorder using zona pellucida protein. Applicants submit that the inventions as claimed can be readily evaluated in one search without placing undue burden on the Examiner. However, in the interest of furthering prosecution of the above-identified patent application, the non-elected claims have been cancelled.



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**Conclusion**

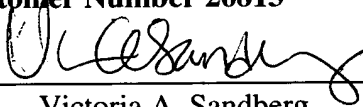
The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number if prosecution of this application may be assisted thereby.

Respectfully submitted,

FAYRER-HOSKEN, ET AL.

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**APPENDIX A - SPECIFICATION/CLAIM AMENDMENTS  
INCLUDING NOTATIONS TO INDICATE CHANGES MADE**

**Serial No.: 10/019,643**

**Docket No.: 235.00300101**

Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted. Additionally, all amendments have been shaded.

4. (Amended) A method for treating or preventing a reproductive [disorder or disease] disease, disorder, or condition in an oocyte-producing organism comprising administering to the organism an immunogenic composition comprising [at least one component selected from the group consisting of (a)] a polypeptide comprising a zona pellucida protein or an immunogenic fragment thereof [and (b) a polynucleotide comprising a nucleotide sequence encoding a polypeptide comprising a zona pellucida protein or immunogenic fragment thereof].
5. The method of claim 4 wherein the oocyte-producing organism is selected from the group consisting of a bird, a fish, a reptile, an amphibian, an insect, an arachnid or an oocyte-producing parasite.
6. (Amended) The method of claim 5 wherein the oocyte-producing organism is a bird and wherein the reproductive disease [or] disorder or condition is selected from the group consisting of egg-binding disease, dystocia, egg-related peritonitis, oophoritis, neoplasia of the reproductive tract, prolapsed oviduct and cloaca, salpingitis, metritis, oviduct impaction, cloacal problems, cystic hyperplasia, ectopic egg formation, [and] chronic egg laying and undesirable behavior as a result of reproductive activity or reproductive problems.
7. (Amended) The method of claim 5 wherein the oocyte-producing organism is a reptile and wherein the reproductive disease, [or] disorder or condition is selected from the group consisting of egg-binding disease, dystocia, egg-related peritonitis, oophoritis, neoplasia of the reproductive tract, prolapsed oviduct and cloaca, salpingitis, metritis, oviduct impaction, cloacal problems, cystic hyperplasia, ectopic egg formation, [and] chronic egg laying and undesirable behavior as a result of reproductive activity or reproductive problems.

8. (Amended) The method of claim 5 wherein the oocyte-producing organism is a fish and wherein the reproductive disease, [or] disorder or condition is selected from the group consisting of egg-binding disease, dystocia, egg-related peritonitis, oophoritis, salpingitis, oviduct impaction and ectopic egg formation.
9. (Amended) The method of claim 5 wherein the oocyte-producing organism is a rabbit and wherein the reproductive disease, [or] disorder or condition is selected from the group consisting of dystocia, peritonitis, neoplasia of the reproductive tract, neoplasia of the mammary glands, metritis [and] cystic hyperplasia and undesirable behavior as a result of reproductive activity or reproductive problems.
12. (Amended) The method of [claims 1, 4 or 10] claim 4 wherein the zona pellucida protein is a glycoprotein.
13. (Amended) The method of [claims 1, 4 or 10] claim 4 wherein the zona pellucida protein is a naturally occurring protein.
14. (Amended) The method of [claims 1, 4 or 10] claim 4 wherein the zona pellucida protein is a recombinant protein or synthetic protein.
15. (Amended) The method of [claims 1, 4 or 10] claim 4 wherein the zona pellucida protein comprises at least one zona pellucida protein selected from the group consisting of a porcine zona pellucida protein and an avian zona pellucida protein.
16. (Amended) The method of [claims 1, 4 or 10] claim 4 wherein the polypeptide further comprises a T cell epitope, a helper T cell or a B cell epitope.

17. (Amended) The method of [claims 1, 4 or 10] claim 4 wherein the immunogenic composition further comprises an adjuvant.
18. The method of claim 17 wherein the adjuvant is selected from the group consisting of Freund's Complete Adjuvant, Freund's Incomplete Adjuvant, Freund's mycotoxin-free adjuvant, aluminum hydroxide, a cell wall extract derived from non-pathogenic *Mycobacteria* spp., a long-chain polydispersed  $\beta(1,4)$  linked mannan polymer interspersed with O-acetylated groups, permulum and synthetic trehalose dicorynomycolate (STDCM).
19. The method of claim 18 wherein the adjuvant is selected from the group consisting of aluminum hydroxide and STDCM.
20. The method of claims 18 wherein the organism is a companion bird, and wherein the adjuvant is aluminum hydroxide.
21. (Amended) The method of [claims 1, 4 or 10] claim 4 wherein the immunogenic composition excludes an adjuvant.
22. The method of claim 21 wherein the oocyte-producing organism is a bird or a reptile.
23. (Amended) The method of [claims 1, 4 or 10] claim 4 wherein the immunogenic composition comprises a zona pellucida protein or immunogenic fragment thereof.
27. (Amended) The method of [claims 1, 4 or 10] claim 4 wherein the immunogenic composition comprises an immunogenic conjugate comprising a zona pellucida protein or a fragment thereof, conjugated to a carrier molecule.

**Appendix A**

Serial No. 10/019,643

Filed: December 28, 2001

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Page 4

28. (Amended) The method of claim [29] 27 wherein the immunogenic conjugate is dually functional.

29. A method for affecting the reproductive system of an oocyte-producing organism comprising administering to the organism an immunogenic composition comprising an immunogenic conjugate comprising a zona pellucida protein or fragment thereof conjugated to a carrier molecule, wherein the oocyte-producing organism is selected from the group consisting of a bird, a fish, a reptile, an amphibian, an insect, an arachnid and an oocyte-producing parasite.